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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,744	09/15/2003	Gin Wu	021218.0009US2	1532

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FISH & ASSOCIATES, PC
ROBERT D. FISH
2603 Main Street
Suite 1000
Irvine, CA 92614-6232

EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

03/04/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rfish@fishiplaw.com
patents@fishiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/662,744	WU, GIN	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/2/2010 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 2/2/2010.
3. In the reply, the applicant amended claim 25, 33-34.
4. Thus, claims 25-34 are pending for examination.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 recites "a drill bit according to claim 25"; however, a drill bit is not recited in claim 25. Further, claim 25 is a method, not an apparatus claim. The Examiner is unsure of the scope of "a drill bit according to claim 25."
7. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Claim 34 recites "The drill bit" of claim 25." Again, claim 25 is a method, not an apparatus claim and fails to disclose a drill bit.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 25,26,28,30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw (US 5,261,818).

Shaw teaches a shaft (13) with a cutting surface (14), a lumen (18), with first (34) and second openings (22) and an open notch (26). Shaw also teaches a method of drilling through bone and injecting a substance through needle (Summary of the invention).

Shaw further teaches a beveled portion with second openings (22) that extend through the beveled portion (Figs 1-6; openings 22 extend through channels 26 that form a beveled tip (the channels form flutes that narrow as they approach 14) that ends at 14 as shown in Fig 4 and Fig 1 where the openings are clearly present along the bevel and the opening clearly extends through). Additionally, the Examiner notes that "a proximal end with a first opening may also be met by opening 20 at the proximal end of the lumen as an alternative to opening 34.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 27 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw.

Shaw teaches the drill as above, but does not teach the length of the drill or the use of a hypodermic needle to inject the substance. It is well known in the art to provide medications in a hypodermic needle/syringe system and to inject the substance in the body. The lumen of the drill bit would be capable of use with a hypodermic needle and one of ordinary skill in the art at the time the invention was made would have expected the device to be used with a hypodermic needle.

Regarding claim 16, Shaw discloses the entire length of the drill is 20-25 mm (0.78-.98 inches). The notches do not extend the entire length of the drill, and appear to extend roughly $\frac{1}{4}$ - $\frac{1}{3}$ the length of the shaft (about 0.19 inches). The examiner believes this is "about 0.1-0.125 inches." Additionally, the drill bit is intended for use in the mouth of a human and therefore must meet some dimensional limits in order to be functional.

1. Claims 29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw as applied to claims above, and further in view of Pshenichny (US 3,750,667).

Shaw does not teach a substantially smooth drill or a drill connected to a shaft as claimed. Pschenichny teaches a medical drill bit for delivering medicament to a space within the bone including a substantially smooth shaft (1), a hub (3), the shaft extending outwardly beyond both proximal and distal ends of the hub (Fig 2) and a lumen extending through the hub (Fig 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the hub and long smooth shaft to Pschenichny better control and handle the bit (hub) and perform injections deeper within the body (longer smooth area).

Response to Arguments

4. Applicant's arguments filed 2/2/2010 have been fully considered but they are not persuasive. It is the examiner's position that to Shaw's openings 22 which are directly located within a beveled tip portion (see above discussion) and extend through to connect to lumen 18. The rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767